

Remarks and Arguments

Claims 21-26 are pending in this case. Claims 22 and 23 have been withdrawn because the Office believes they are drawn to non-elected subject matter. Claim 21 has been amended to more particularly point out the invention. The amendment is supported throughout the specification, for example, page 2, lines 9-11, and lines 17-19; page 4, lines 1-10; page 14, lines 8-12; page 18, line 4-page 20, line 27; page 23, lines 6-18; Figures 1, 2, and 9. New claims 27-28 have been added to further point out the invention. Support for the new claims is found in the specification for example, page 4, lines 20-37, and page 11, lines 21-30.

35 U.S.C. § 112

Claims 21 and 24-26 stand rejected under 35 U.S.C. § 112 as allegedly not enabled. The Office states that the specification discloses a plurality of marker genes that appear to be more abundantly expressed in undifferentiated hES cell lines compared to differentiated hES cell lines. The Office also states that the specification discloses a plurality of marker genes that appear to be less abundantly expressed in undifferentiated hES cells compared to differentiated cells. Moreover, the Office admits that Examples 4, 5, and 8 demonstrate high level expression of PODXL in undifferentiated hES cells and decreased PODXL expression after growing the undifferentiated hES cells in unconditioned media (Office Action dated May 11, 2007, page 3). Nonetheless, the Office still alleges that the claims are not enabled.

Applicants have amended claim 21 and believe the amended claim addresses all of the Office's concerns. With respect to the allegation that mRNA does not necessarily correspond to protein level expression Applicants note that the specification discloses that the data obtained by quantitative rtPCR (mRNA)(Table 4) was confirmed by flow cytometry (Figure 8) (protein expression) for Oct 4. Applicants further note that the specification discloses that PODXL is a trans-membrane protein and thus expressed on the cell surface (page 20, lines 24-27) confirming the findings of Hara et al. (1999) *Immunity* 11:567 made of record in this case in a Supplemental Information Disclosure Statement filed on July 2, 2007. Hara isolated the murine homolog of PODXL. Hara

discloses correspondence between mRNA expression and protein expression ("Consistent with previous reports . . . we detected PCLP1 mRNA in kidney, heart") (Hara page 568, 2nd column). Hara goes on to say that PCLP1 was detected by immuno-staining in aorta-gonad-mesonephros cultures (page 569, 2nd column) and by immunohistochemical staining of the dorsal aorta (page 570, 2nd column). Thus heart cells, according to Hara, express both protein and mRNA of the murine homolog of PODXL. Lastly, Applicants note that there is nothing of record to support the position taken by the Office with respect to mRNA and protein expression. The Office is reminded of its burden this regard:

It is incumbent upon the Patent Office, whenever a rejection on this basis [enablement] is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure **and to back up its assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement, *In re Marzocchi* 169 U.S.P.Q. 367, 369 (CCPA 1971)(emphasis added).**

Applicants note that no evidence has been submitted by the Office supporting its position and the reasoning is contradicted by data provided in the specification and the disclosure of Hara et al.

CONCLUSION

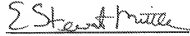
In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Customer No. 22869
Appl. No. 10/804,822
September 11, 2007

Atty. Docket No. 135/003P
Amendment and Response with RCE

Please grant any extensions of time required to enter this filing and charge any additional required fees to our deposit account No. 07-1139 referencing the docket number indicated above.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "E. Stewart Mittler", written over a horizontal line.

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September 11, 2007

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